designated with a Ph.C. license and may provide expanded clinical services. Since July 2000, a similar credentialing process has existed in North Carolina, where a pharmacist may apply to become a clinical pharmacist practitioner (CPP) so long as he/she meets the criteria specified by the state (also detailed in the Background section of this document).[49]

At the federal level, a pharmacist practicing within the Indian Health Service (IHS) or Bureau of Prisons (BOP) may be recognized by the National Clinical Pharmacy Specialist (NCPS) Program as someone who has met the qualifications necessary for the provision of high-level care.[28] This program, established in 1997, ensures uniform clinical competency and recognizes advanced scopes of practice for Public Health Service (PHS) pharmacists through the establishment of credentialing standards and adequate training and education programs for clinical pharmacists.

These certification and credentialing processes serve as a way to not only recognize pharmacists who practice in advanced clinical scopes, but also to ensure that the public has a means to identify those pharmacists who are authorized to provide clinical services. In this way, patients can feel confident in their ability to choose competent practitioners without the potential for fraud in that decision.

4. **Does a potential for fraud exist because of the inability for third party payors to determine competency?**

As stated above, there should be no potential for fraud in the ability of third party payors to determine competency of pharmacists practicing within a traditional scope due to the licensing process required by each State Board. In the determination of competency for pharmacists who practice within expanded scopes, some state Medicaid programs have specified credentials or qualifications necessary for pharmacists to be recognized as billable providers. In this way, the Centers for Medicare and Medicaid Services (CMS) and other third party payors who follow CMS payment structures can assure that only qualified pharmacists are compensated for clinical services, thus decreasing the potential for fraudulent reimbursement. For example, in New Mexico, Pharmacist Clinicians can apply to become Medicaid providers eligible for reimbursement based on the level of service provided.[28] Additional examples of Medicaid programs that provide compensation based on cognitive services by pharmacists exist in Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina.[19,28] To date there is no evidence to suggest there have been problems with the ability of those Medicaid programs to determine competency of the pharmacists they choose to reimburse for clinical services.

5. **Is the public seeking greater accountability of this group?**

In general, there is no evidence to suggest the public is seeking greater accountability of pharmacists with or without expanded scopes of practice compared to any other health professional group. Pharmacists have historically been and are consistently ranked among the most trusted professions in public opinion polls. In the most recent Gallup poll on the

honesty and ethics of various professions, pharmacists ranked 2nd behind nurses as the professionals with the highest level of honesty and ethical standards.[50]

**Specialized Skills and Training**

1. **Are there currently recognized or emerging specialties/levels within this profession?**

   **Yes. There are many recognized specialties within the profession.**
   [NOTE: DHP Healthcare Workforce Data Center's *Virginia's Licensed Pharmacist Workforce:* 2011 report provides information obtained directly from Virginia's on education, post-graduate credentials, post-graduate residency 1 and 2, specialty board certifications, and other non-board certifications. A copy of this report is being available on the Board of Health Professions' website (www.dhp.virginia.gov/bhp for reference for this study.]

   In the 1960s clinical pharmacy began to emerge as a specialty within the profession. Several schools of pharmacy outside of the innovator programs in California began to offer two-year post-baccalaureate doctor of pharmacy degree programs in the 1970s. Over the subsequent 20 years these programs grew to represent career options for almost 30% of all graduating pharmacists. One of the goals of transitioning the entry level educational requirements of all schools and states in the 1990s from a bachelor's degree to the Doctor of Pharmacy degree as the sole entry-level degree was to increase clinical training for students to better prepare them for direct patient care practice.[17] The curriculum includes didactic and introductory and advanced experiential education in a variety of areas such as direct patient care, systems management, and public health.[11,17] The professional competencies and educational outcomes achieved through completion of a Doctor of Pharmacy degree prepares graduates to enter pharmacy practice in any setting.[9] Beyond the requirements for a degree and licensure, pharmacists can voluntarily pursue post-licensure experiences and certification to develop specialized skill sets and further knowledge. Since the practice of pharmacy occurs in different settings and pharmacists have differences in training and certification, many specialties have emerged within the profession.

   The structure for the recognition of specialties within the profession has been in place for over 30 years. The Board of Pharmaceutical Specialties (BPS) was established in 1976 as an independent certification agency of the American Pharmacists Association.[51] The first specialty certifications developed by BPS were nuclear pharmacy (1978), nutrition support (1988), and pharmacotherapy (1988). There are also several independent multidisciplinary organizations that have recognized pharmacist as specialists as well.

   Emerging specialties have been recognized by the ACCP with the creation of Practice and Research Networks (PRNs) of which there are currently 22 networks.[52] The formation of PRNs is predicated on the submission of endorsement by 50 plus individuals who practice within the given area. In several cases the creation of PRNs preceded the establishment of a BPS recognized specialty (Table 1). Several pharmacists have also been recognized as fellows in specialty medical societies such as American College of Clinical Pharmacology, American Society of Nephrology, and Society for Critical Care Medicine.

Table 1. ACCP Practice and Research Networks

| Practice and Research Networks (PRNs) | Year Established | Members (No.)[a] |
|---|---|---|
| Adult Medicine | 1999 | >750 |
| Ambulatory Care | 1992 | 1100 |
| Cardiology | 1993 | 796 |
| Central Nervous System | 1993 | 171 |
| Clinical Administration | 2001 | >200 |
| Critical Care | 1992 | 1034 |
| Drug Information | 2002 | 223 |
| Education and Training | 2002 | 285 |
| Emergency Medicine | 2008 | 50 |
| Endocrine and Metabolism | 2005 | 182 |
| Geriatrics | 1995 | 244 |
| GI/Liver/Nutrition | 2000 | 145 |
| Health Outcomes | 1994 | 142 |
| Hematology/Oncology | 1994 | >500 |
| Immunology/Transplantation | 1993 | 235 |
| Infectious Disease | 1998 | >1000 |
| Nephrology | 1993 | 180 |
| Pain and Palliative Care | 2000 | 235 |
| Pediatrics | 1993 | 405 |
| Pharmaceutical Industry | 1998 | 255 |
| Pharmacokinetics/Pharmacodynamics/Pharmacogenomics | 1997 | ~130 |
| Women's Health | 1994 | ~140 |

[a]Membership as of 2008 from accp.com individual PRN History document

**a. If so what are they? How are they recognized? By whom and through what mechanism?**

There are a variety of options for post-licensure education and training, which allows pharmacists to qualify for advanced practice positions or begin to specialize in specific practice areas. Pharmacists can obtain on-the-job training, opt to prepare for competency-based examinations, or partake in training programs.[17] There are certificate programs, specialty residency programs, certification programs, and finally board certification.

**Certificate programs** also known as practice-based continuing pharmacy education activities are available for pharmacists to gain additional competencies. These activities are a combination of didactic instruction and a practice

experience, which allows the pharmacist to evaluate the acquired skills.[53] Examples of certificate training programs for pharmacists include pharmacy-based immunization delivery, pharmaceutical care for patients with diabetes, pharmacy-based lipid management, and medication therapy management services developed by the American Pharmacists Association.[54]

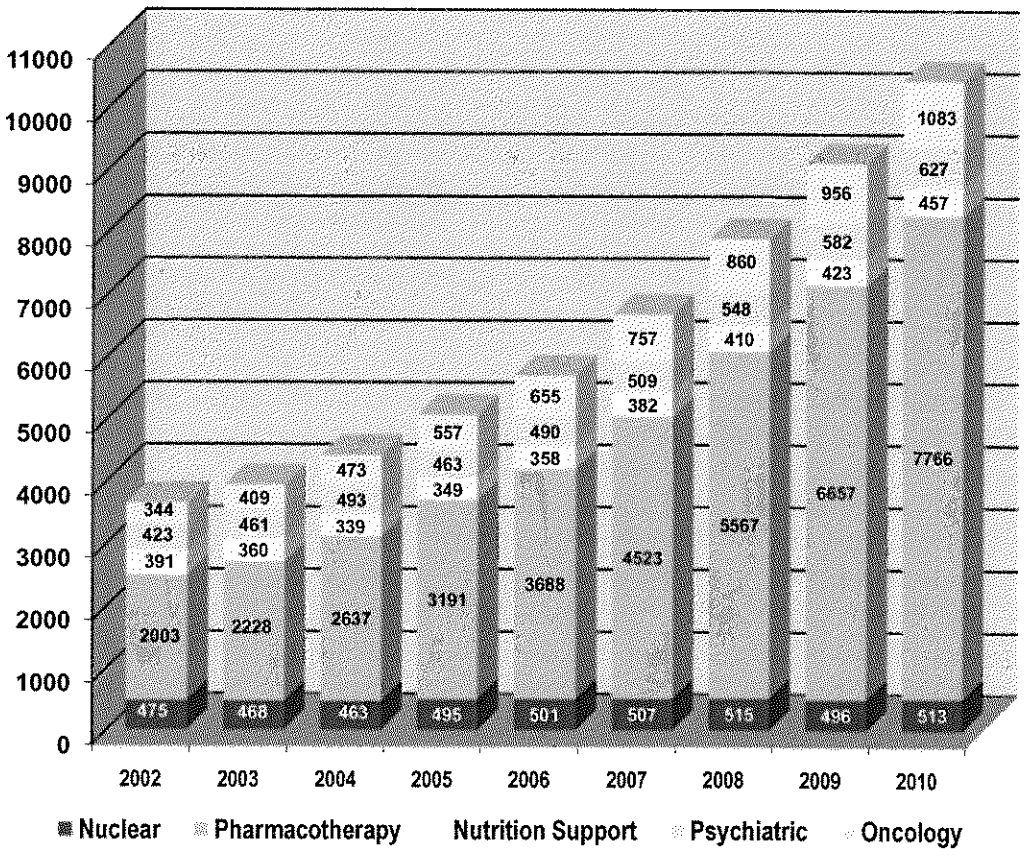
**Pharmacy residency programs** are post-licensure training programs designed for pharmacists to accelerate growth beyond entry-level competencies while remaining under the supervision of more experienced practitioners.[55] Specifically, a postgraduate year one pharmacy residency (PGY1) expands the general competencies in managing medication-use systems and supports optimal medication therapy outcomes in patients with a variety of disease states.[55] PGY1 residency experiences can occur in a variety of settings as long as residents meet the core required outcomes established by the American Society of Health-System Pharmacists (ASHP). Some pharmacists will choose to continue on to a postgraduate year two pharmacy residency program. PGY2 residency programs increase residents' depth of knowledge, skills, and level of expertise of medication management and clinical leadership in a specialized area of practice.[55] A PGY2 program prepares residents for board certification if available in the focused practice area. Some of the specialty areas where PGY2 residencies exist include critical care, oncology, health-system pharmacy administration, pediatrics, and other settings or patient populations. ASHP is responsible for accreditation of residency programs. The ASHP Commission on Credentialing develops the standards for residency programs. Completion of residency programs provides pharmacists with the training and experience to obtain advanced positions in direct patient care and team based care.

There are multiple pharmacist-specific certification opportunities. Certified Geriatric Pharmacists are pharmacists who have met the requirements and passed an examination demonstrating advanced competencies to provide care for the geriatric population.[56] Compounding pharmacy is another specialty area of pharmacy. Currently, compounding pharmacists can gain recognition by International Academy of Compounding Pharmacists.[57]

Pharmacists can pursue **board certification** and earn other credentials that designate increased competencies in specialty areas. These credentials may be specific to pharmacists or multidisciplinary. The Board of Pharmacy Specialties (BPS) was established in response to the expanding roles for pharmacists in specialized areas and need for a process to identify and evaluate the knowledge and skill sets.[51] Currently, BPS recognizes six specialties: ambulatory care pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pharmacotherapy, and psychiatric pharmacy. Board certification in these specialty areas occurs after passing a psychometrically sound examination. Each specialty area has its own eligibility requirements and examination content outlines describing the domains, tasks, and knowledge statements. Content outlines are validated and examinations are psychometrically sound and legally defensible.

Individual pharmacists who are board certified practitioners can attain board approved additional qualifications that designate advanced knowledge and skill in a focused area within the BPS recognized specialty. For example, a board certified pharmacotherapy specialist can obtain added qualifications in infectious disease or cardiology. Each specialty maintains its own recertification processes. The figure below depicts the number of pharmacists certified by BPS from 2002 to 2010.[51] The ambulatory care examination was first held in 2011, therefore, it is not represented in this figure.

Pharmacists Certified by the Board of Pharmaceutical Specialties *




*As reported by BPS, February 2011

Beyond pharmacy-specific certification, pharmacists can participate in multidisciplinary certification programs.[58] Listed below are the credentials pharmacists may earn and the credentialing body in parentheses.

- Certified Anticoagulation Care Provider (National Certification Board for Anticoagulation Providers)
- Certified Asthma Educator (National Asthma Educator Certification Board)

- Accredited in Clinical Pharmacology (American Board of Clinical Pharmacology)
- Certified Diabetes Educator (National Certification Board for Diabetes Educators)
- Board Certified-Advanced Diabetes Management (American Nurses Credentialing Center)
- Clinical Lipid Specialist (Accreditation Council for Clinical Lipidology)
- Certified Nutrition Support Clinician (National Board of Nutrition Support Certification)
- Certified Pain Educator (American Society of Pain Educators)
- Credentialed Pain Practitioner (American Academy of Pain Management)
- Certified Specialist in Poison Information (American Association of Poison Control Centers)
- Diplomat of the American Board of Applied Toxicology (American Board of Applied Toxicology)
- Advanced Cardiac Life Support (American Heart Association)
- Pediatric Advanced Life support (American Heart Association)

**b. Are they categorized according to function? Services performed? Characteristics of clients/patients? Combination? Other?**

The pharmacy specialties can be categorized based on the functions or services provided, as well as the characteristics of the patient population. For example nuclear pharmacists are responsible for the preparation and dispensing of radioactive drugs for use in the diagnosis and treatment of diseases.[17] Another pharmacy specialty defined by its function is compounding pharmacy. Sometimes commercially manufactured medications are not acceptable for a specific patient or completely unavailable. Compounding pharmacists can prepare a product tailored to the specific needs of patients.

Some pharmacy specialties can be categorized by the service performed. For example, pharmacists provide medication therapy management services to optimize therapeutic outcomes for patients. Other specialty pharmacy areas defined by the services provided include drug information and immunizations.

The most common categories are specialty practice areas based on disease states or patient population. The pharmacists' role in all settings included ensuring safe and appropriate therapy and outcomes, but the differences occur in the practice areas. For example, pediatric pharmacists and geriatric pharmacists specialize in specific patient populations. Other pharmacists specialize in specific practice areas such as psychiatry or oncology.

**c. How can the public differentiate among these specialties or levels?**

Traditionally, the public is most familiar with the community pharmacist who evaluates, fills, dispenses, and counsels the patient on a drug product prescribed

by their doctor or dentist. The roles of community pharmacists are expanding to include providing immunizations, blood pressure assessment, hemoglobin A1c assessment, cholesterol assessment, and medication therapy management as well as disease state management services. The patient may realize those in the profession who have this specialty in part when they are referred by their doctor or through advertisements in the media. Thus the public may be able to differentiate pharmacists who have earned specialty status based on the functions and services provided as well as the specialty credentials they have earned. For example, patients may seek out a compounding pharmacist for the preparation of a specialized product specific to their needs.

The public does not routinely come in contact with pharmacists who practice in specialty settings such as family practice clinics or as members of interdisciplinary teams in health systems. However, in other health professions, the public has no problem differentiating among specialties. For example, a patient does not question a referral to physical therapists or endocrinologists. Therefore the public should not have difficulty differentiating among pharmacist specialties.

**Autonomous Practice**

1. **What is the nature of the judgments and decisions that Pharmacists are currently entitled to make in practice in Virginia? Does this differ in states with more expanded scope of practice? If so, how?**

    a. **In assuring safe medication use?**

    Pharmacists in Virginia and elsewhere must use their clinical judgment, expertise in pharmacotherapy, and evidence-based medicine to assure safe medication use for all patients. When receiving a prescription or medication order, a pharmacist must make an assessment regarding the validity of the prescription or order; the patient's need for the prescription and/or other therapies such as immunizations, over the counter medications, etc.; the appropriateness of the indication, dose, dosage form, frequency, and duration of therapy; and the potential for drug-drug, drug-disease, drug-food, or other interactions. The pharmacist must then make decisions regarding whether or not to fill the prescription or verify the order; what, if any, generic substitution can be made; the level of counseling the patient may need; what, if any, referrals may be indicated; and what parameters need to be monitored to assess for safety and efficacy.

    Many of the functions that are specifically outlined in § 54.1-3320 of the Code of Virginia regarding acts to be performed by a pharmacist (refer to page 15) reflect the duty pharmacists have to ensure safe medication use, as well as the decisions they must make to do so.[46]

    The general nature of judgments and decisions that pharmacists must make to assure safe medication use is similar across states, even in states with more expanded scopes of practice.

    b. **In determining or approving treatment plans?**

    Pharmacists in Virginia and elsewhere must use clinical judgment, patient assessment skills, expertise in pharmacotherapy and pharmacokinetics, and primary and secondary literature in order to determine and approve treatment plans for individual patients. This is particularly true for community pharmacists that practice within a collaborative drug therapy management model, as discussed in earlier sections of this document. In general, pharmacists that work with physicians as part of a collaborative practice agreement do have greater responsibility and autonomy when it comes to determining appropriate pharmacotherapy options and treatment plans for their patients.

    In institutional settings, clinical pharmacists are often tasked with developing protocols or nomograms for the use of certain (typically high-risk) medications or medication classes, which usually include drug selection recommendations, dosing recommendations, drug administration guidelines, and monitoring parameters that should be followed. In hospitals and health systems that utilize

computerized physician order entry (CPOE) systems, pharmacists are also often involved in the development of care sets, which group medications that are typically used together as part of a treatment plan.

The nature and scope of decisions that can be made regarding treatment plans are more extensive in states such as New Mexico and North Carolina that have expanded scopes of practice for pharmacists, as discussed in the Scope of Practice section.

**c. In directing or supervising others in patient care?**

While pharmacists do supervise others (pharmacy technicians, interns, and students) who perform functions related to the preparation and dispensing of medications, they do not typically direct or supervise other practitioners who are directly and immediately involved in patient care.

**2. Which functions typically performed by Pharmacists in Virginia are *unsupervised* (i.e., neither directly monitored nor routinely checked)?**

**a. What proportion of the practitioner's time is spent in unsupervised activity?**

The majority of pharmacists' time is spent on unsupervised activity that is not directly monitored or routinely checked, so long as it is within the scope of practice for pharmacists in Virginia. This is true for both dispensing and non-dispensing functions, which include, but are not limited to: assessing prescriptions and medication orders for accuracy; ensuring their appropriateness and safety with regards to indication, dose, frequency, etc.; checking for drug-drug, drug-food, drug-disease, and drug-allergy interactions; processing prescriptions and medication orders; preparing medications for dispensing and/or delivery; counseling patients on their medications; and helping patients with the selection of over-the-counter medications and herbals.[17]

Clinical functions that are performed independently and unsupervised by some pharmacists, particularly in primary care, long-term care, and/or acute care settings, include: patient assessment; medication profile review; drug level monitoring; immunization; obtaining and evaluating vital signs such as blood pressure, heart rate, and respiratory rate; and performing point of care tests such as blood glucose, cholesterol, INR, etc. that are waived by the Clinical Laboratory Improvement Amendments (CLIA).[17]

In institutional settings, pharmacists also independently perform tasks related to medication use and health systems management, such as: drug inventory control; monitoring of patient outcomes; reporting of medication errors and adverse events; and the development of protocols, nomograms, and guidelines for medication use within the system.

**b. Who is legally accountable/liable for acts performed with no supervision?**

As with other health care professionals, each individual pharmacist is responsible and legally accountable for duties performed with no supervision.

**3. Which functions are performed *only under supervision* in Virginia?**

**a. Is the supervision *direct* (i.e., the supervisor is on the premises and responsible) or *general* (i.e., the supervisor is responsible but not necessarily on the premises?**

Some pharmacists in the state of Virginia practice under the general supervision of other health care providers/prescribers. Pharmacists in Virginia who have entered into collaborative practice agreements with a physician, osteopath, or podiatrist are thereby authorized to perform additional functions under their general supervision. According to the Virginia Board of Pharmacy and Board of Medicine Regulations for Collaborative Practice Agreements, "'Agreement' means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of §54.1-3300.1 of the Code of Virginia."[59]

According to the Regulations, a practitioner of medicine, osteopathy, or podiatry authorizes the activities that a pharmacist can engage in as part of the agreement. However, the actions authorized as part of the treatment protocol are generally performed with a high degree of independence and autonomy. As such, the general supervision of the practitioner does not replace legal accountability and responsibility for the actions each individual pharmacist performs within the scope of the agreement.

**b. How frequently is supervision provided? Where? And for what purpose?**

The frequency with which supervision is provided is highly variable and dependent on the collaborative practice agreement between the practitioner and pharmacist. Factors that may influence the degree of supervision include the practice setting and the types of patients and disease states typically encountered by the pharmacist on behalf of the practitioner. This supervision is typically provided on-site if the pharmacist is integrated into the physician practice or via telephone or electronic correspondence with the practitioner if they are not integrated into the same practice. The purpose of such general supervision would be to allow for consultation with the practitioner if necessary and to ensure appropriate care for the patient if his/her needs extended beyond the scope of what the pharmacist could provide.

**c. Who is legally accountable/liable for acts performed under supervision?**

Each healthcare professional involved in a collaborative practice agreement is legally accountable/liable for actions performed within their scope of practice.

**d. What is contained in a typical supervisory or collaborative arrangement protocol?**

The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (NABP), most recently updated in August 2011, addresses the general content that should be included in a collaborative pharmacy practice agreement.[60]

A typical collaborative arrangement protocol should clearly identify the practitioner(s) and pharmacist(s) involved and the effective date of the agreement. It should outline the types of decisions the pharmacist is allowed to make, including: a detailed description of the types of diseases, drugs, or drug categories involved, and the activities allowed in each case; a detailed description of the methods, procedures, decision criteria, and plan the pharmacist should follow when conducting allowed activities; and a detailed description of the documentation procedures the pharmacist is to follow with regards to documenting, communicating, and reporting the specific decisions made. The protocol should outline a method for the practitioner to monitor compliance with the agreement and clinical outcomes, and a plan to intercede where necessary. It should also have a description of the continuous quality improvement program used to evaluate effectiveness of patient care and ensure positive patient outcomes. Finally, the agreement should include provisions for the practitioner to override decisions made by the pharmacist when he/she deems it necessary and/or appropriate, and provisions for either party to cancel the agreement by written notification.[60]

Activities that the pharmacist may be responsible for as part of such an agreement may include collecting and reviewing patient medication histories; measuring patient vital signs; ordering pertinent laboratory tests and interpreting the results; and the modification, continuation, or discontinuation of drug therapy per the protocol established as part of the agreement.

**4. Do Pharmacists typically supervise others? Describe the nature of this supervision?**

Pharmacists in Virginia and elsewhere typically supervise others as part of their practice. Pharmacists are required by Virginia law to directly supervise pharmacy technicians and pharmacy interns that practice under their responsibility. While pharmacy technicians and interns are responsible for a variety of functions such as computer data entry, medication preparation and compounding, inventory control, etc., the supervising pharmacist serves as the final check for many of these functions and is legally responsible for the care and safety of patients.

There is a Pharmacist-in-Charge (PIC) who is responsible for the general supervision of others who practice at any given practice location. In institutional and hospital settings, there are a number of managerial levels wherein pharmacy administrators and directors serve as general supervisors for other pharmacists and technicians employed by the department. This supervision is typically administrative in nature and not meant to be a direct supervision of the patient care activities of each individual pharmacist.

5. **Describe the typical work settings, including supervisory arrangements and interactions of the practitioner with other regulated and unregulated occupations and professions.**

Pharmacists work in a number of different settings, each of which presents unique opportunities for interaction with different regulated and unregulated occupations. These settings include community pharmacies, hospitals and health systems, primary care clinics, long-term care facilities, nursing homes, assisted living facilities, hospice facilities, nuclear pharmacies, schools of pharmacy, federal health agencies, research facilities, managed care organizations (MCO's), pharmacy benefit managers (PBM's), and mail-order pharmacies. Some examples of regulated professions that pharmacists interact with in these settings include physicians, nurses and nurse practitioners, physician assistants, social workers, nutritionists, behavioral counselors, physical and occupational therapists, and dentists. In many of these settings, pharmacists also interact with pharmacy technicians, another regulated profession, in a supervisory capacity. Some examples of unregulated professions that pharmacists interact with in these settings include cashiers, secretaries, care partners, and volunteers.

6. **Are patients/clients *referred to* pharmacists for care or other services? By whom? Describe a typical referral mechanism.**

Physicians and other practitioners often refer patients to community pharmacists for dispensing of prescriptions, compounding of unique drug formulations, counseling services, immunizations, management of minor ailments, and help with selection of over-the-counter medications and durable medical equipment. In Virginia and other states, primary care practitioners and specialists also refer patients to primary care clinics that have pharmacists integrated into their practice model. For example, the VA system and many academic medical centers have anticoagulation clinics, diabetes clinics, etc. which are primarily pharmacist-run. As part of collaborative practice agreements, some primary care physicians refer patients to a pharmacist for the management of chronic diseases like hypertension, diabetes, heart failure, asthma, etc. They may also refer patients with complicated medication regimens or issues with adherence for more focused medication management by a pharmacist.

In a September 2011 report, the Alliance for Patient Medication Safety (APMS) and the National Alliance of State Pharmacy Associations (NASPA) recently highlighted the work of Michelle Thomas, PharmD, CDE, who used the SuperioRx Care Adherence Discovery grant to establish a collaborative arrangement with a community primary care

physician office in rural Virginia.[61] The project allowed for the referral of certain patients to the pharmacist for cholesterol and diabetes management through education and medication management where appropriate. The pharmacist was available one day per week for referrals, which were made by two physicians at the site, nurse practitioners, and physician assistants. At the end of the six-month trial period, both the physicians and patients surveyed felt satisfied with the program and agreed that the pharmacist-provided services were making a significant impact in improving patient health and wellness.[61] This project provides just one example of a successfully implemented referral mechanism that allowed for the provision of pharmacist services to eligible patients who were identified by physicians and other providers in the community setting.

7. **Are patients/clients *referred from* pharmacists to other? Describe a typical referral mechanism. How and on what basis are decisions made to refer?**

**As the most accessible health professionals in the community, pharmacists are frequently available to assess and triage patient care needs and thereby refer them to others for care.** Pharmacists refer patients to physicians and other practitioners for services that cannot be reasonably or safely provided by a pharmacist. For example, in the community setting, patients often come to pharmacists for counseling and recommendations regarding over-the-counter medications and herbals. The pharmacist may discover during the consultation or screening that the problem is not amenable to self-care and may refer the patient to a physician for a full assessment. In the primary care setting, a pharmacist may be assessing a patient during a visit for medication therapy management or chronic disease follow-up and notice physical symptoms that are suggestive of an acute process (infection, deep vein thrombosis, stroke, etc.) requiring physician assessment and care. The pharmacist would then refer the patient to a physician or other practitioner for evaluation.

According to one survey of over 500 pharmacist preceptors, students and faculty members at the Virginia Commonwealth University, 64% of respondents referred patients to another health care provider, usually a physician, at least daily. Less commonly reported referrals were to dieticians (38%), behavioral health clinicians (30%), specialty practice pharmacists (26%), physical therapists (20%), and chiropractors (13%).[62]

One example of a successful pharmacist referral mechanism in the community setting in the state of Virginia was described in Project ImPACT: Osteoporosis.[63] As a result of health-promotion and disease-prevention efforts at 22 Ukrop's pharmacies – a regional supermarket chain pharmacy in Richmond, VA – pharmacists screened a total of 532 patients for osteoporosis using bone mineral density (BMD) screening. Of 305 patients that were reached for follow-up, 37% were identified as having high risk for fracture, while 33% were identified as having moderate risk and 30% as having low risk. As a result of the pharmacists' screening and referral efforts, 37% of patients in the moderate- and high-risk categories subsequently completed a physician visit, 19% had a diagnostic scan, and 24% were initiated on osteoporosis therapy. In addition to the positive patient care outcomes that were reported, the study also confirmed that patients were willing to

pay for pharmacy-based osteoporosis screening and that third-party payers were willing to compensate pharmacists for collaborative community health management services.[63]

Decisions to refer patients are based on the clinical judgment of the pharmacist, the resources and time available to the pharmacist, and, in the case of collaborative practice agreements, the limitations of the protocol that specifies which activities are authorized to the pharmacist.

**Scope of Practice**

1. **Which existing functions of this profession in Virginia are *similar to* those performed by other professions? Which profession(s)?**

   Some of the functions of pharmacists are similar to those of other health care professionals.[22,23] In addition to nurses and physicians, pharmacists participate in taking medication histories and performing medication reconciliation. Physicians and other mid-level prescribers select the product and doses of medications for patients. In many settings pharmacists are actively involved in drug therapy selection and determining individualized dosing regimens based on pharmacokinetic and pharmacodynamic characteristics. Pharmacists often perform physical assessments similar to nurses and physicians. Pharmacists can assess blood pressure, perform point of care tests such as INR assessment for patients on warfarin therapy, and check blood sugar for diabetics to name but a few. Similar to nurses, pharmacists can administer vaccinations in accordance with state laws.[54] Pharmacists, similar to dieticians and nutrition specialists, can determine nutrition needs for patients and determine nutrition treatment plans. Often, pharmacists and nutrition specialists collaborate to continuously monitor patients especially those who need chronic nutritional support. Often there is overlap in the functions of health professionals due to utilization of team-based care models.

2. **What additional functions, if any, are performed by Pharmacists in other states?**

   Although Virginia has established regulations for the creation of collaborative practice agreements, other states and countries have been more progressive in expanding the scope of practice for pharmacists. [Note: the phrase "more progressive" above constitutes commentary.]

   Several state Medicaid programs, including Washington, Wisconsin, Mississippi, Iowa, Tennessee, Arizona, Minnesota, South Dakota, Missouri, New Mexico, and North Carolina had waivers approved to allow for contract pharmacist-related compensation for clinical services and more states are following.[19] Since being recognized as providers by Medicaid in 2005, pharmacists in Minnesota can be reimbursed for providing medication management services to eligible patients once enrolled with Minnesota Health Care Programs and after completion of an approved certification program on medication management. An ASHP document summarizes pharmacist provider status in 11 state health programs. It highlights the different paths taken to create and implement programs, the variety of patient populations served, and billing and reimbursement mechanisms. To attain pharmacist provider status in some of these state programs, pharmacists may need additional credentials such as additional training or certification. Most of the programs were state Medicaid programs, however, one program in Ohio was operated by the state Department of Health's Bureau for Children with Medical Handicaps.[64]

   Nationally, the NCPS program expanded the functions of Indian Health Service pharmacists by recognizing them as primary care providers with prescriptive authority.[20] Similar expanded functions exist for Veterans Affairs pharmacists.[21] Currently, in both

North Carolina and New Mexico, pharmacists may seek advanced practice designations resulting in increased scope of practice including prescribing authority.[7,8] Since 1993, New Mexico pharmacists have the opportunity to pursue additional training and earn the designation Pharmacist Clinician. Pharmacist Clinicians may obtain personal DEA numbers and have prescriptive authority under a supervising physician. The Clinical Pharmacist Practitioner Act of 2000, established the designation Clinical Pharmacist Practitioners (CPP). A CPP provides disease therapy management and can initiate, modify, or substitute therapies under a broad collaborative practice agreements.

The DEA has also granted prescriber numbers to pharmacists working in institutions under collaborative practice agreements with physicians in five additional states (California, Massachusetts, Montana, North Dakota, and Washington).[28] In these states, DEA-registered pharmacists are recognized as mid-level practitioners and may prescribe controlled substances.

Prescribing authority has been expanded to pharmacists in both Canada and the United Kingdom.[65,66] Pharmacists in the United Kingdom can gain prescriptive privileges as Pharmacist Supplementary Prescribers. Supplementary prescribers establish an individualized, patient-specific clinical management plan (CMP) with an independent prescriber such as a doctor or dentist. Once the CMP is created, supplementary prescribers may treat the conditions diagnosed by the independent prescriber and prescribe both non-controlled and controlled medications. Canadian provinces are also expanding the scope of pharmacy practice. In Alberta, different prescribing categories exist for pharmacists after completing orientation and registration on the Alberta College of Pharmacist's clinical registry. Pharmacists may adapt prescriptions by modifying the dose or drug formulation based on organ function, availability, perform therapeutic substitution for patient-specific reasons, or issue a prescription for continuity of care until primary prescriber is contacted. Pharmacists may also prescribe during an emergency where immediate therapy is necessary and seeing another prescriber is unreasonable. Lastly, pharmacists may gain additional prescribing authority based on collaborative practice agreements.

**3. Which functions of this profession are *distinct from* other similar health professions in Virginia? Which profession(s)? In other states?**

The functions of the pharmacy profession that are distinct from other health professionals include: evaluation of prescriptions to assure compliance with state and federal statutes, the process of medication dispensing, monitoring the sale of over the counter controlled substances and pseudoephedrine, etc. The pharmacist dispensing process includes utilizing evidence-based literature and guidelines combined with patient-specific information to verify that the medication order is safe and effective for the patient.[17] Pharmacists conduct prospective drug utilization reviews in the medication dispensing process. By performing this review, pharmacists identify drug-related problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse. If problems are identified, pharmacists utilize their drug knowledge expertise to collaborate with prescribers to

resolve the identified issues. The pharmacist then prepares, compounds, or repackages the medication to be dispensed to patients. In the community setting, pharmacists are responsible for counseling patients on the prescribed medication. Institutional pharmacists also provide counseling for patients being discharged with newly prescribed medications or medication regimen changes.

Pharmacists are also largely responsible for procuring and storing medications. Pharmacists may also enter into collaborative practice agreements with physicians resulting in a team approach for patient care. In both the ambulatory and inpatient settings, pharmacists are often called upon to determine an individualized dosage regimen for patients with renal or liver dysfunction or assisting in therapeutic drug monitoring. For example, pharmacists in anticoagulation clinics manage drug therapy by monitoring and making interventions such as dose modification as needed.

Pharmacists in specialty areas may have distinct functions unique to their practice. A distinct function of compounding pharmacists is preparing an individualized product specific to the needs of the patient. All patients in long-term care facilities or hospitals must have their drug regimens reviewed by a pharmacist at least once per month. Often, this is a function of consultant pharmacists.

## Economic Costs

1. **What are the range and average incomes of members of this profession in the Commonwealth? In adjoining states? Nationally?**

   Below are average annual incomes and ranges for pharmacists in Virginia, adjoining states, and nationally, according to May 2010 data from the Bureau of Labor Statistics.[67] All ranges reported represent the 10th to 90th percentile of incomes.

   Table 2. Annual Pharmacist Income (2010) – Average and Range

| State or Region | Average Annual Income | Annual Income Range |
|---|---|---|
| Virginia | $113,800 | $91,210 - $140,810 |
| North Carolina | $112,970 | $88,170 - $142,100 |
| West Virginia | $111,950 | $80,430 - $142,720 |
| Tennessee | $112,130 | $86,840 - $141,290 |
| Maryland | $104,880 | $77,110 - $132,750 |
| District of Columbia | $114,340 | $92,330 - $144,490 |
| National | $109,380 | $82,090 - $138,620 |

   The incomes in Virginia are comparable to the range and average incomes for pharmacists in adjoining states. Pharmacists in the mid-Atlantic states, including Virginia, have a slightly higher income overall than the national average.

2. **If the data are available, what are the typical fees for service provided by this profession in Virginia? In adjoining states? Nationally?**

   Pharmacists' primary revenue for services provided are dispensing fees, which are added onto the cost of the medication product and are predominantly set by third party payors, including state Medicaid and Medicare Part D plans. Dispensing fees vary from one private insurance plan to another and from state to state. Typically, dispensing fees paid by Medicaid fall in the $3 to $5 range.[68]

   Reimbursement for cognitive services provided by pharmacists is less common, so not much data is available regarding fees and payment for clinical services in Virginia. Some pharmacists in Virginia and elsewhere conduct point of care testing (blood glucose measurements, blood pressure, etc.) for which they charge a fee that is typically paid out of pocket by the patient. Fees charged by pharmacists for such services vary markedly among practice settings and geographic locations, so there is no reliable source for obtaining data on these values.

   Currently, pharmacists are eligible to receive some compensation for medication therapy management (MTM) services provided once per year to Medicare Part D patients, as outlined in the Medicare Prescription Drug Improvement and Modernization Act of 2006. There are however a number of restrictions in place that have limited patient participation in and pharmacist reimbursement for these services. Additionally, some state Medicaid programs do recognize pharmacists as providers and compensate them for MTM services. The payment structures vary from state to state but typically depend on the acuity and

complexity of care provided. For example, under the Minnesota MTM program, pharmacists are able to bill Medicaid $52 for the provision of level 1 (straightforward) care, and up to $148 for level 5 (high complexity) care.[69]

In a 2005 review of existing MTM services and compensation models that are being used by both public and private sector programs, the Lewin Group was able to develop a model for payers to use in compensating pharmacists for MTM services.[70] The report found that the majority of payment systems currently in use are variants of fee-for-service (FFS), while in some settings, pharmacists are billing "incident to" the physician for clinical services provided by the pharmacist. Through interviews conducted with pharmacists, pharmacy benefit providers, health plans, and policy makers, the group also found that while payment amounts varied widely among the different programs, several interview respondents suggested a "rule of thumb" payment rate of $2 to $3 per minute for pharmacist-provided MTM services.[70]

**3. Is there evidence that expanding the scope of Pharmacist would**

**a. Increase the cost for services?**

There are numerous examples in the literature that point to cost savings for institutions, CMS, and other third party payors secondary to expanding the scope of practice for pharmacists. To date, no study that has evaluated cost or return on investment as an outcome measure has presented evidence to suggest increased cost for services as a result of increasing patient care privileges for pharmacists. On the contrary, the literature has pointed to cost containment and overall cost savings secondary to reduced number of hospitalizations, emergency visits, outpatient visits, specialty visits, and drug-related morbidity and mortality.

Schumock, et al.[71,72] and Perez, et al.[73] conducted multiple studies from 1988-2005, including an extensive literature review by Schumock, et al.[71] of 104 articles, that evaluated the economic impact of clinical pharmacy services. These services included disease management, general pharmacotherapeutic monitoring, pharmacokinetic monitoring, targeted drug programs, and general patient education programs and cognitive services. The investigators found that over the period from 1988-2005, each dollar invested in clinical pharmacy services resulted in an overall average benefit gain of $10.07 per $1 of allocated funds. The benefit to cost ratio for this time period ranged from a low of $1.02:$1 to a high of $75.84:$1, illustrating that even at the ratio's lowest level there was still an economic benefit to investing in clinical pharmacy services.

As another example, Brennan, et al.[74] published a study in early 2012 that estimated a $3:$1 return on investment for integrating pharmacy interventions aimed at improving medication adherence in patients with diabetes. The more than $600,000 in health care cost avoidance resulted from improved adherence rates and increased initiation of appropriate therapies. This study was conducted in patients using CVS retail pharmacies or a Caremark mail order pharmacy to fill

their prescriptions, thereby illustrating the applicability of this cost-savings data to other large retail or mail order chains.

As stated, there is an extensive collection of peer-reviewed publications evaluating the cost-effectiveness of delivery of patient care services by pharmacists in a variety of settings. Many of the studies are summarized nicely in Appendix B (pp 66-77) of the 2011 Report to the U.S. Surgeon General.[28]

**b. Increase salaries for Pharmacist employed by health delivery organizations?**

There is currently no information available to determine how pharmacist salaries might be affected by expanding their scope of practice within different health delivery organizations. Any fluctuation in pharmacists' salaries would likely be affected by the specific setting and its current payment structure.

**c. Restrict other professions in providing care?**

[NOTE: Commentary]

There is no evidence to suggest that expanding the scope of practice for pharmacists would restrict other professions in providing care. The expertise and services brought by a clinical pharmacist to the primary, acute, or long-term care environment would be complementary to those of other professions, not competitive. When pharmacists take a more active role in providing medication therapy management, chronic disease management, and assessment of minor ailments, it frees up time for physicians and other practitioners to focus on more critically ill patients who may need more in-depth physician assessment.

In 2010, the NCPS Program developed a survey that sought input from IHS physicians on the clinical and administrative impact of primary care and disease management services by pharmacists. Of the 117 physicians that responded, 96% of providers reported some benefit in improved disease management outcomes, increased return on investment, increased patient access to care, or allowing the physician to shift their workload to more critical patients.[28]

Additionally, as outlined earlier in the Background section, the U.S. Surgeon General has endorsed the PHS report "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice" and has called on health leadership to optimize the role of pharmacists and utilize collaborative practice models to improve health care delivery in all settings.[43] This endorsement gives further weight to the idea that pharmacist services will enhance, not restrict, the ability of all members of the health care team to deliver quality care while containing costs and increasing access to care.

The physician-pharmacist collaborative practice model has been in existence for decades, although not utilized to its full capacity, and so far there has not been reason to believe other professions are restricted in providing care because of this model.

**d. Have other deleterious economic effects?**

As stated previously, no study that has evaluated cost or return on investment as an outcome measure has suggested increased cost for services or other deleterious economic effects as a result of expanding the scope of practice for pharmacists. While there might be an initial increase in prescription drug spending secondary to initiation of therapies and increased adherence, total health care spending decreases over the long run due to more preventative services and less drug-related morbidity and mortality, costly hospitalizations, specialty referrals, etc. There is also an indirect cost savings related to decrease in the number of sick days from work and increased productivity secondary to improved health outcomes.

4. **Address issues related to supply and demand and distribution of resources.**
[NOTE: Commentary]
As discussed in the Background section, there is currently a primary care workforce shortage that is impacting patient access to care all over the United States. This shortage is only projected to get worse as more patients gain access to health insurance while less medical internists decide to practice in primary care, opting instead for more lucrative careers in specialty areas of medicine.

One solution for addressing the need for more primary care providers is to expand the scope of practice for pharmacists, who are in arguably the best position among all health care professionals to be able to fill the void left by decreasing numbers of primary care physicians. Pharmacists have the education, training, and expertise to be able to take a more active role in increasing access to primary care services, and the current supply of pharmacists into the workforce can support that role. The number of pharmacy school graduates in the U.S. has been climbing steadily over the last 10 years, partly in response to pharmacist shortages in the late 1990's, and now sits at about 10,500 graduates per year.[75] By expanding the scope of practice for pharmacists, creating pharmacy jobs that are integrated into primary care models, and pushing for proper reimbursement mechanisms for clinical services provided, many of these new pharmacy graduates could enter the primary care workforce and help respond to the growing demand for these services.

5. **Are third-party payors in Virginia currently reimbursing services provided by pharmacists? Directly to the Pharmacist? Employer?**

Third party payors in Virginia are not currently reimbursing pharmacists or their employers for clinical services provided by pharmacists. As discussed previously, Medicare, through various pharmacy benefits managers (PBMs), does compensate pharmacists directly for one MTM session per patient per year. However there are many restrictions regarding eligibility that limit patient participation in these sessions.

In comparison, some other states have third party payors and Medicaid programs that do recognize pharmacists as providers and compensate them for MTM services through PBMs. One example is Outcomes Pharmaceutical Health Care[76], which contracts with PBMs to allow for the delivery, documentation, and billing of MTM services by pharmacists. As previously mentioned, the payment structures vary from state to state but typically depend on the acuity and complexity of care provided.

6. **Are similar services to those provided by pharmacists also provided by another non-physician profession? Which profession(s)? Are they reimbursed directly by third-party payors?**

Similar clinical services are provided by other non-physician professionals such as nurse practitioners and physician assistants (see section on Scope of Practice for additional information). These services are currently being reimbursed directly by third party payors, as most third party payors (including Medicaid) do recognize these non-physician practitioners as mid-level providers who may bill for clinical services.

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## Appendix A. PharmD Curricula (2011-2012) from Virginia Schools of Pharmacy

### Virginia Commonwealth University School of Pharmacy

**P1 Fall Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| MEDC | 527 | Basic Pharmaceutical Principles for the Practicing Pharmacist | 3.0 |
| PCEU | 507 | Pharmaceutics & Biopharmaceutics I | 3.0 |
| PHAR | 509 | Evidence Based Pharmacy I (Drug Info) | 1.0 |
| PHAR | 510 | Medication Use Systems | 1.0 |
| PHAR | 512 | Health Promotion & Disease Prevention | 2.5 |
| PHAR | 513 | Contemporary Pharmacy Practice | 2.5 |
| PHAR | 525 | Communications in Pharmacy Practice | 2.0 |
| MEDC | 550 | Scholarship I | Continues |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 523 | Foundations I | 1.0 |
| PHAR | 530 | IPPE I: Community I | 1.0 |
| | | **Semester Total** | **17.0** |

**P1 Spring Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PCEU | 508 | Pharmacokinetics | 2.0 |
| PCEU | 509 | Pharmaceutics & Biopharmaceutics II | 2.5 |
| MEDC | 533 | Pharmacognosy | 2.0 |
| MEDC | 543 | Clinical Chemistry for the Pharmacist | 2.0 |
| MEDC | 553 | Clinical Therapeutics Module I: Intro to Medicinal Chemistry | 1.0 |
| PHTX | 606 | Clinical Therapeutics Module II: Introduction to Pharmacology | 1.0 |
| PHAR | 529 | Clinical Therapeutics Module III: Intro to Special Populations | 1.0 |
| PHAR | 540 | Self-care, Alternative and Complementary Treatments | 3.0 |
| PHAR | 545 | The U.S. Health Care System | 2.5 |
| PHAR | 547 | Managing Professional Patient-centered Practice | 1.0 |
| MEDC | 550 | Scholarship I | 1.0 |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 524 | Foundations II | 1.0 |
| PHAR | 531 | IPPE II: Community II | 1.0 |

| | | | |
|---|---|---|---|
| | | **Semester Total** | **21.0** |

**P2 Fall Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PHAR | 565 | Evidence Based Pharmacy II: Research Methods & Statistics | 2.5 |
| PHAR | 566 | Evidence Based Pharmacy III: Literature Evaluation | 2.0 |
| MEDC | 605 | Biotechnology, Pharmacogenomics & Pharmacogenetics | 2.0 |
| PHAR | 567 | Pharmacy Informatics | 1.5 |
| PHAR | 544 | Clinical Therapeutics Module IV: Cardiovascular | 4.5 |
| PHAR | 555 | Clinical Therapeutics Module V: Endocrinology | 2.5 |
| PHAR | 556 | Clinical Therapeutics Module VI: Neurology I | 3.0 |
| PCEU | 550 | Scholarship II | Continues |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 534 | Foundations III | 1.0 |
| PHAR | 532 | IPPE III: Hospital | Continues |
| | | **Semester Total** | **19.0** |

**P2 Spring Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PCEU | 615 | Applied Pharmacokinetics | 2.0 |
| PHAR | 621 | Pharmacoeconomics | 2.0 |
| PHAR | 622 | Epidemiology & Pharmacy Practice | 2.0 |
| PHAR | 623 | Patient Medication Safety | 2.0 |
| PHAR | 601 | Clinical Therapeutics Module VII: Neurology II | 1.0 |
| PHAR | 602 | Clinical Therapeutics Module VIII: Psychiatry | 3.0 |
| PHAR | 603 | Clinical Therapeutics Module IX: Respiratory/Immunology | 3.0 |
| | | Electives | 2.0 |
| PCEU | 550 | Scholarship II | 2.0 |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 535 | Foundations IV | 1.0 |
| PHAR | 532 | IPPE III: Hospital | 1.0 |
| | | **Semester Total** | **21** |

**P3 Fall Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PHAR | 660 | Pharmacy Practice Management I - Community Practice | 4.0 |
| PHAR | 604 | Clinical Therapeutics Module X: Infectious Diseases | 4.5 |
| PHAR | 605 | Clinical Therapeutics Module XI: Hematology/Oncology | 2.5 |
| PHAR | 606 | Clinical Therapeutics Module XII: Nephrology/Urology | 2.5 |
| PHAR | 607 | Clinical Therapeutics Module XIV: Dermatology/EENT | 1.5 |
| | | Electives | 2.0 - 3.0 |
| PHAR | 550 | Scholarship III | Continues |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 640 | Foundations V | 1.0 |
| PHAR | 533 | IPPE IV: Clinical Patient Care | Continues |
| | | **Semester Total** | **18.0 - 19.0** |

**P3 Spring Semester**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PHAR | 661 | Pharmacy Practice Management II - Institutional Practice | 2.0 |
| PHAR | 618 | Clinical Therapeutics Module XIII: Gastrointestinal/Nutrition | 2.5 |
| PHAR | 619 | Clinical Therapeutics Module XV: Women's Health/Bone, Joint | 2.5 |
| PHAR | 620 | Clinical Therapeutics Module XVI:Toxicology/Critical Care | 2.0 |
| PHAR | 721 | Clinical Therapeutics Module XVII: Special Populations | 1.0 |
| PHAR | 724 | Pharmacy Law | 3.0 |
| | | Electives | 2.0 - 3.0 |
| PHAR | 550 | Scholarship III | 2.0 |
| PHAR | 771 | Student Pharmacist Professionalism | Continues |
| PHAR | 645 | Foundations VI | 1.0 |
| PHAR | 533 | IPPE IV: Clinical Patient Care | 1.0 |
| | | **Semester Total** | **19.0 - 20.0** |

**P4 Year**

| Department | Course Number | Course Title | Course Credit |
|---|---|---|---|
| PHAR | 760 | Acute Care Pharmacy Practice I | 5.0 |
| PHAR | 761 | Advanced Hospital Pharmacy Practice | 5.0 |
| PHAR | 762 | Geriatrics Pharmacy Practice | 5.0 |
| PHAR | 763 | Ambulatory Care Pharmacy Practice | 5.0 |
| PHAR | 765 | Elective I | 5.0 |
| PHAR | 766 | Elective II | 5.0 |
| PHAR | 768 | Advanced Community Pharmacy Practice | 5.0 |
| PHAR | 771 | Student Pharmacist Professionalism | 1.0 |
| PHAR | 773 | Acute Care Pharmacy Practice II | 5.0 |
| | | **Annual Total** | **41.0** |

## Hampton University School of Pharmacy

**First Year Professional**

| **Fall Semester** | **Credits** | **Spring Semester** | **Credits** |
|---|---|---|---|
| Pharmaceutics I | 5 | Pharmaceutics II | 4 |
| Pharmaceutics Lab I | | Pharmaceutics Lab II | 1 |
| Anatomy & Physiology | 4 | Medicinal Chemistry I | 4 |
| Anatomy & Physiology Lab | 1 | Biostats/Literature Evaluation | 3 |
| Pharmaceutical Care I | 3 | Pharmaceutical Care II | 3 |
| Physiological Chemistry | 3 | | |
| Profession of Pharmacy IV | 2 | | |
| **Total:** | **18** | **Total:** | **15** |

| **Summer Session** | **Credits** | |
|---|---|---|
| Community IPPE | 1 | (2 weeks - 80 hrs.) |
| **Total:** | **1** | |

**Second Year Professional**

| **Fall Semester** | **Credits** | **Spring Semester** | **Credits** |
|---|---|---|---|
| Pharmacokinetics | 5 | Health Care Admin. II | 3 |
| Medicinal Chemistry II | 4 | Pharmaceutical Care IV | 3 |
| Microbiology/Immunology | 4 | Intro to Clerkships | 2 |

| | | | | | |
|---|---|---|---|---|---|
| Health Care Admin. I | | 2 | DDM I* | | 3 |
| Pharmaceutical Care III | | 3 | DDM II* | | 3 |
| | | | DDM III* | | 4 |
| | **Total:** | **18** | | **Total:** | **18** |

*Drug and Disease Management

| **Summer Session** | | **Credits** | |
|---|---|---|---|
| Institutional IPPE | | 1 | (3 weeks - 120 hrs.) |
| | **Total:** | **1** | |

**Third Year Professional**

| **Fall Semester** | | **Credits** | **Spring Semester** | | **Credits** |
|---|---|---|---|---|---|
| Pharmaceutical Care V | | 3 | Pharmacy Law & Ethics | | 2 |
| Patient Assessment | | 1 | Pharmacy Practice Lab | | 4 |
| Patient Assessment Lab | | 1 | DDM VII | | 4 |
| DDM IV | | 3 | DDM VIII | | 4 |
| DDM V | | 3 | Professional Elective (2) | | 4 |
| DDM VI | | 4 | | | |
| Research Methods | | 1 | | | |
| Professional Elective (1) | | 2 | | | |
| | **Total:** | **18** | | **Total:** | **18** |

| **Summer Session** | | **Credits** | |
|---|---|---|---|
| Elective IPPE | | 1 | (3 weeks - 120 hrs.) |
| | **Total:** | **1** | |

**Fourth Year Professional**

| **Three Semester Period** | | **Credits** |
|---|---|---|
| PHA 650 | Seminar I | 1 |
| PHA 651 | Seminar II | 1 |
| PHA 652 | Seminar III | 1 |
| PHA 670 | Community Pharmacy Practice Experience* | 5 |
| PHA 671 | Institutional Pharmacy Practice Experience* | 5 |
| PHA 672 | Community/Institutional Pharmacy Practice Experience* | 5 |
| PHA 683 | Geriatrics** | 5 |
| PHA 685 | Administration/Management** | 5 |
| PHA 690 | Internal Medicine I | 5 |

| | | |
|---|---|---|
| PHA 691 | Ambulatory Care I | 5 |
| PHA 692 | Ambulatory Care II | 5 |
| PHA 693 | Pediatrics** | 5 |
| PHA 694 | Psychiatry** | 5 |
| PHA 695 | Drug Information** | 5 |
| PHA 696 | Elective | 5 |
| PHA 699 | Internal Medicine II | 5 |

*Any (2) of the (3)
**Any (1) of the (5)

**Total 43.0 over 3 semesters (Summer, Fall, & Spring)**

## Shenandoah University Bernard J. Dunn School of Pharmacy

### First Professional Year (P1)

| FALL | Credit Hrs. | SPRING | Credit Hrs. |
|---|---|---|---|
| PHAR 501: Introduction to Pharmacy Practice | 3 | PHAR 512: Pharmaceutics II | 4 |
| PHAR 508: Pharmaceutics I (Calculations) | 2 | PHAR 513: Pharmaceutics II Lab | 1 |
| PHAR 516: Introductory Pharmacy Practice Experience I | 1 | PHAR 517: Introductory Pharmacy Practice Experience II | 2 |
| PHAR 518: Patient Counseling/Communications | 2 | PHAR 527: IBHS IV: Cardiovascular | 2 |
| PHAR 523: IBHS I: Biocompounds and Biochemistry | 2 | PHAR 528: IBHS V: Immunology, Respiration, Digestion | 2 |
| PHAR 524: IBHS II: Endo, Skin, Bone, Muscle | 2 | PHAR 529: IBHS VI: Renal, Reproduction, Development | 2 |
| PHAR 525: IBHS III: Nervous System | 2 | PHAR 530: IBHS: Lab II | 1 |
| PHAR 526: IBHS: Lab I | 1 | PHAR 534: Essentials of Pharmacogenomics | 3 |
| PHAR 531: Psychosocial Aspects of Disease | 2 | | |
| **Semester Total** | **17** | **Semester Total** | **17** |

### Second Professional Year (P2)

| FALL | Credit Hrs. | SPRING | Credit Hrs. |
|---|---|---|---|
| PHAR 600: Pharmacokinetic Principles | 3 | PHAR 601: Drug Literature Evaluation | 2 |
| PHAR 603: Basic Principles of Pharmacology | 3 | PHAR 602: Drug Literature Evaluation Lab | 1 |
| PHAR 604: Nonprescription Products | 2 | PHAR 607: ICARE: Respiratory | 2 |
| PHAR 605: Outpatient Pharmacy Practice Lab | 1 | PHAR 608: ICARE: Renal | 2 |
| PHAR 617: Pharmacotherapy Outcomes | 1 | PHAR 619: ICARE: Cardiovascular | 4 |
| PHAR 627: Clinical Research Methods/Biostatistics | 3 | PHAR 632: Applied Pk and PGx I | 1 |
| PHAR 628: Clinical Research Methods/Biostatistics Lab | 1 | PHAR 655: Introductory Pharmacy Practice Experience III | 2 |
| General Elective | 3 | Professional Elective(s) | 3 |

| | | | |
|---|---|---|---|
| **Semester Total** | **17** | **Semester Total** | **17** |

**Third Professional Year (P3)**

| **FALL** | **Credit Hrs.** | **SPRING** | **Credit Hrs.** |
|---|---|---|---|
| PHAR 701: ICARE: Endocrine/Reproduction | 2 | PHAR 700: ICARE: GI/Nutrition | 2 |
| PHAR 704: Professional Practice Management I | 3 | PHAR 708: ICARE: Musculoskeletal | 2 |
| PHAR 709: ICARE: Hematology/Oncology | 3 | PHAR 712: Professional Practice Management II | 3 |
| PHAR 718: ICARE: Infectious Disease | 3 | PHAR 713: Sterile Compounding Lab | 1 |
| PHAR 723: Patient Assessment I | 2 | PHAR 717: Pharmacy Law | 3 |
| PHAR 725: Introductory Pharmacy Practice Experience IV | 1 | PHAR 720: ICARE: Neuro/Psychiatry | 3 |
| PHAR 733: Applied Pk and PGx II | 1 | PHAR 724: Patient Assessment II | 2 |
| Professional Elective(s) | 3 | PHAR 734: Applied Pk and PGx III | 1 |
| | | PHAR 735: Introductory Pharmacy Practice Experience V | 1 |
| **Semester Total** | **18** | **Semester Total** | **18** |

**Fourth Professional Year (P4)**

| **FALL** | **Credit Hrs.** | **SPRING** | **Credit Hrs.** |
|---|---|---|---|
| PHAR 800: Ambulatory Care APPE | 5 | PHAR 803: In-Patient Acute Care APPE | 5 |
| PHAR 801: Community Clinical APPE | 5 | PHAR 806: Selective APPE | 5 |
| PHAR 804: Institutional APPE | 5 | PHAR 807B: Selective II APPE | 3 |
| PHAR 807A: Selective I APPE | 2 | PHAR 808: Advanced Pharmacy APPE | 5 |
| PHAR 825: Pharmacy Practicum APPE | 1 | | |
| **Semester Total** | **18** | **Semester Total** | **18** |
| | | **PROGRAM TOTAL** | **140** |

**Appalachian College of Pharmacy**

**Fall Semester: P1 curriculum**

PHA 0100 Introduction to Pharmacy and Health Care Systems 3 Credits
PHA 0112 Cellular Biology and Biochemistry 6 Credits
PHA 0130 Principles of Immunology and Hematology 2 Credits
PHA 0120 Pharmaceutical Calculations 3 Credits
PHA 0125 Pharmaceutics and Biopharmaceutics 4 Credits
PHA 0140 Communication and Professional Development 2 Credit
**Total Credits: 20 hours**

**Spring Semester: P1 curriculum**
PHA 0135 Introduction to Jurisprudence and Pharmacy Law 1 credit
PHA 0150 Autonomic Nervous System /Central Nervous: Medicinal Chemistry and Pharmacology 5 Credits
PHA 0155 Gastrointestinal Pharmacology and Medicinal Chemistry 2 Credits
PHA 0160 Cardiovascular, Renal, and Pulmonary: Pharmacology and Medicinal Chemistry 4 Credits
PHA 0200 Applied Clinical Pharmacokinetics 2 Credits
PHA 0175 Pharmaceutics Lab I 1 Credit
PHA 0180 OTC Products 2 Credits
PHA 1010 EPPE I 1 Credit
PHA 0195 P1 Pharmacy Milestone Examination 0 Credits (pass/fail)
**Credit hours: 18 hours**

**Summer Semester: P2 curriculum**
PHA 2010 CPPE I 3 Credits
PHA 2020 CPPE II 3 Credits
PHA 0145 Introduction to Anti-infective Agents 4 Credits
PHA 0165 Endocrine System: Pharmacology and Medicinal Chemistry 3 Credits
PHA 0170 Clinical Toxicology 1 Credits
PHA 0210 Drug Information, Clinical Research, and Biostatistics 3 Credits
**Total Credits: 17 hours**

**Fall Semester: P2 curriculum**
PHA 0220 Diseases of the Renal System and Fluid and Electrolyte Disorders 4 Credits
PHA 0225 Diseases of the Immune System, Skin and Connective Tissue Disorders 3 Credits
PHA 0282 Diseases of the Neurological System and Psychiatric Disorders 6 Credits
PHA 0242 Diseases of Cardiovascular and Respiratory Systems 6 Credits
PHA 0250 Patient Assessment and Case Studies I 1 Credit
PHA 0260 Pharmaceutics Lab II 1 Credit
PHA 2030 EPPE II 1 Credit
Elective 1 Credit
**Total Credits: 23 hours**

**Spring Semester: P2 curriculum**
PHA 0232 Infectious Disease 5 Credits
PHA 0275 Diseases of the Gastrointestinal System, Disorders of Nutrition and Metabolism and Bariatrics 4 Credits
PHA 0270 Diseases of the Hematological System and Oncological Disorders 5 Credits
PHA 0215 Pharmacy Administration 3 Credits
PHA 0251 Patient Assessment and Case Studies II 1 Credit
PHA 2040 EPPE II 1 Credit
PHA 0298 P2 Pharmacy Milestone Examination 0 Credits (pass/fail)
Elective 1 Credit
**Credit hours: 20 hours**

**Summer Semester: P3 curriculum**
PHA 0265 Disease of the Endocrine and Reproductive System 4 Credits
PHA 0290 Pharmacotherapeutic Considerations in Special Populations (Pediatrics, Geriatrics, Pregnancy/Lactation) 4 Credits
PHA 0300 Advanced Jurisprudence and Pharmacy Law 2 Credits
**Credit hours: 10 hours**

**PHA 3010-3080 APPE I through VIII, 5 Credits Each**
PHA 3010 Community Health and Wellness
PHA 3020 Hospital/Health System Pharmacy
PHA 3030 Community Patient Care
PHA 3040 Ambulatory Care
PHA 3050 Acute Care, Inpatient and General Medicine
PHA 3060 APPE Elective
PHA 3070 APPE Elective
PHA 3080 APPE Elective
PHA 0399 P3 Pharmacy Milestone Examination 0 Credits (pass/fail)
**Credit hours: 40 hours**

**Review of Potential Pharmacist Scope of Practice Barriers to the Development of Effective Team Approaches to Healthcare Delivery in Virginia**

**SUMMARY OF PUBLIC COMMENT**
**AS OF AUGUST 17, 2012**

Below is a summary of the comments received by the Board office between the Public Hearing held on July 23rd and August 17th in order of receipt.

**Oral Comment at the Public Hearing, July 23, 2012**

One speaker, who represented the Virginia Pharmacy Congress, presented oral comment during the Public Hearing. The following 21 points detail the comment as well as response to questions posed by the Regulatory Research Committee and staff.

**Janet A. Silvester, RPh, MBA, FASHP, Director of Pharmacy and Emergency Services, Martha Jefferson Hospital, Charlottesville, VA – speaking on behalf of the Virginia Pharmacy Congress**

1. Virginia Pharmacy Congress (VPC) had been in existence since 1998 and consists of the Virginia Society of Health System Pharmacists, Virginia Pharmacist Association, the Virginia Association of Chain Drug Stores, Virginia Commonwealth University School of Pharmacy, Appalachian College of Pharmacy, Hampton University School of Pharmacy, Shenandoah School of Pharmacy, and Epic Pharmacies.
2. Two representatives from the Virginia Board of Pharmacy serve as ex officiate of directors.
3 VPC's mission is to serve as a catalyst to advance the pharmacy profession in Virginia through discussion, understanding and action, regarding matters of common interest to Virginia pharmacists, pharmacy organizations and institutions, and constituencies served with respect to professional, education, ethical, technological, legislative, and regulatory issues.
4. VPC has reviewed the Virginia Health Reform Initiative Advisory Council's December 2010 report and is supportive of the report's statement related to changing scope of practice laws to permit more health professionals to practice up to the evidence based limit of their training. VPC agrees that Virginia is facing serious access to care issues and that pharmacists are uniquely positioned to be part of the solution due to their accessibility in the community and their education and training.
5. VPC's written response to the study workplan is intended to inform the work of the Committee.
6. VPC believes that improving patient care and health system outcome can be realized through advanced pharmacy practice. VPC holds that pharmacists are significantly underutilized in the health care delivery system and that when pharmacists are integrated into direct patient care through collaborative practice with physicians or other members of the health care team, patient outcomes are improved. Evidence is cited from Chisholm and



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Burns, et al. (2010),[1] an extensive systematic review and analysis of 298 research studies. This review demonstrates improved patient outcomes across health care settings and disease states, in inpatient settings, with reduced re-admissions, length of hospital stay, and mortality. Improved clinical markers were demonstrated in ambulatory care settings for patients with diabetes, heart failure, hypertension, and dyslipidemias, among other chronic diseases.

7. The 2011 report to the U.S. Surgeon General[2] describes the management of diseases following initial diagnosis, through a number of patient care services that pharmacists deliver in a variety of practice settings through collaborative practice agreements. Services discussed included performing or obtaining necessary health and functional status assessments, initiating or discontinuing treatment to manage disease according to therapeutic goals agreed upon by the primary provider and the patient. They also involved ordering, interpreting, and monitoring laboratory tests, formulating clinical assessments and developing therapeutic plans, documentation, and communication of essential information about the care delivered to other appropriate healthcare provider. Patient and caregiver education and training to enhance understanding and the appropriate use of medications and adherence with treatment regimens were also noted as were providing care, coordination, and services for wellness and disease prevention.
8. Ms. Silvester asked that a specific recommendation be made to revise the existing regulations for collaborative practice agreements in Virginia. She indicated that they want to work with the Medical Society of Virginia and Virginia Nurses Association in this process as they did when the original collaborative practice agreement language was introduced in 1998.
9. Ms. Silvester indicated that the 2011 report to the Surgeon General referenced earlier also indicates that medications are involved in 80 percent of all treatments and that drug-related morbidity and mortality are estimated to cost the U.S. $200B per year. She further strongly suggested that expanded roles for pharmacists as part of a collaborative health care team could significantly improve the human and financial impact associated with adverse drug outcomes. She notes that pharmacists can help improve access to care and the quality and safety of medication use. She further indicates that the value of interdisciplinary collaboration must be enhanced to realize the best patient outcomes as a result of each team member providing their specific expertise to assure that quality care is delivered.
10. In follow-up, Ms. Silvester was specifically asked whether the VCA is seeking to be able to initiate and modify prescription. She replied that that would be part of the

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[1] Chisholm-Burns, M. A., Kim Lee, J., Spivey, C.A., Slack, M., Herrier, R.N., Hall-Lipsy, E., Graff Zivin, J., Abraham, I., Palmer, J., Martin, J.R., Kramer, S. and Wunz, T. (2010). US pharmacists' effect as team members on patient care: Systematic review and meta-analyses. *Medical Care*, 48 (10), 923-933. Accessible through http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists__Effect_as_Team_Members_on_Patient.10.aspx?WT.mc_id=HPxADx20100319xMP

[2] Giberson, S., Yoder, S, Lee, M.P. (2011). Improving patient and health system outcomes through advanced pharmacy practice. U. S. Public Health Service, Dec. 2011. Accessible through http://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists__Effect_as_Team_Members_on_Patient.10.aspx?WT.mc_id=HPxADx20100319xMP



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recommendation sought, within the context of collaborative agreements based upon agreed upon protocols between the provider and pharmacist.

11. When followed-up further as to whether statutory change would be needed, Ms. Silvester indicated that VCA would expand on this further in written comment to be submitted after the hearing. However, the intent is to add initiation of therapy.
12. Ms. Silvester was asked whether VCA had information on any difference in the incidence of malpractice in North Carolina and New Mexico, states which permit initiation of therapy, in comparison with other states. She indicated that they did not. Neither did staff.
13. Ms. Silvester was asked about the training pharmacists receive in managing disease and order plans, and the criteria required such is the case for physician assistants or nurse practitioners. Ms. Silvester indicated that written comment is to be provided subsequent to the public hearing that will articulate expectations about credentials and training in addition to the workplan response that previously provided the schools of pharmacy curricula. She noted that with regard to initiation of therapy, pharmacist training best prepares the practitioner. She further indicated that the comments would refer to how recent a pharmacist's training was and how it relates to the existing curriculum. It would speak to years of experience, residency training, board certifications, program accreditation and other means of assuring appropriate credentials.
14. Ms. Silvester was asked how the patient would be made aware of the coordination of their care, team membership, and who is making decisions. Ms. Silvester indicated that sharing information is essential and referred to previous personal experience of a pharmacist she knew who has worked with primary care physician practices under collaborative practice. Their patients were made aware that the pharmacist was part of the team and helping with management of disease states.
15. Ms. Silvester was asked to expand on the pre-requisite coursework required prior to entering pharmacy school that would be of greatest relevance to initiating therapy, especially microbiology, physiology and anatomy. She reported that VCA would be sure to include this information in the written comments
16. When asked whether there were any concerns among the pharmacy community on the potential to require a separate certification similar to North Carolina's or New Mexico's provisions. Ms. Silvester indicated that there were differences of opinion. Practitioners who had been out of school for many years may have concern about how to demonstrate specific competencies. She noted that additional certification could help validate the knowledge and skill necessary for safe practice and reported that the written comment would articulate expectations related to education.
17. In response to a question concerning who bears ultimate responsibility for patient care, Ms. Silvester indicated that, in her view, the physician is a team leader, and there are delegated duties to the other team members, but they still share accountability for care. She noted that part of the protection for the physician is that there is an agreement in advance concerning treatment protocols. Unusual circumstances would prompt conversation between the team members.
18. When asked whether expanded practice authority would be limited to management of chronic diseases, Ms. Silvester responded that that VPC had not made a final determination.

Patients frequently present with multiple morbidities and some have complex issues that make their therapeutic regimens more challenging.

19. When asked whether pharmacists with advanced practice authority should be limited to Schedule VI (non-opioid medications), Ms. Silvester responded that they should also be permitted the full range of prescriptive medications.
20. When asked if pharmacists should be incorporated not only into primary and health systems patient care teams, but expanded practices at the local retail pharmacy, Ms. Silvester responded that the issue relates primarily to patient need and access and effective therapeutic management across settings as patients transition regardless of location. She noted that the ready accessibility of pharmacies for most patients make them a good portal for the underserved.
21. When asked if current collaborative practice agreements can be strengthened without consideration of prescriptive authority, Ms. Silvester responded that the current language requires a specific agreement between a pharmacist and a physician. If the pharmacist was going to support a primary care practice with multiple physicians, he would have to have a separate agreement with each rather than the practice as a whole. The original language was created in 1998, and the way that care is delivered today is very different than then.

**Written Comment**

**Janet Silvester - July 24, 2012**

Ms. Silvester wished to clarify that the Virginia Pharmacy Congress is seeking including "initiation of therapy" only within the context of a mutually agreed upon collaborative practice agreement that rests on protocols and treatment plans that have been agreed upon in advance.

They are not seeking independent prescriptive authority. Their desire is to work within a team based model of care that is best for the patient and healthcare system as a whole.

**Timothy S. Musselman, Pharm.D., Executive Director, Virginia Pharmacists Association - August 17, 2012**

Dr. Musselman supports the following changes to increase utilization of collaborative practice agreements:

1. Allow patients the choice of opting **out** of collaborative agreements rather than requiring them to "opt **in**,"
2. Add disease-state specific protocols rather than patient-specific ones,
3. Allow collaborative agreements to include all patients under the care of a physician or physician group. The medical director of a group practice could authorize practice-wide collaborative agreements which better reflect the growing culture of expanding group practices through evolving Accountable Care Organizations and Patient Centered Medical Home team models,
4. Include nurse practitioners and physician assistants to be specifically listed as authorizers of agreements in addition to physicians, and

5. Allow the use of electronic protocols.

**Dawn Havrda, PharmD, FCCP, BCPS, Professor and Chair, Department of Pharmacy Practice, Shanandoah University, Dunn School of Pharmacy – August 17, 2012.**

Dr. Harva cites the increase in demand due to health care reform and the projected physician shortage, noting that pharmacists are academically prepared, ready, and able to work with physicians to help address the anticipated "health care void."

Dr. Harva notes that current collaborative agreements may relate to treatment using drug therapy, laboratory tests, or medical devices to improve patient outcomes using a specific protocol. She echoes Dr. Musselman's recommendations #1 through #5, above, and adds that "implementation" and/or "initiation" of drug therapy should be provided as an option in collaborative agreements between the pharmacist and physician for post-diagnosis management of a medical condition. She notes that pharmacists are uniquely positioned to work in conjunction with physicians in managing drug therapy of a chronic disease state and indicates all options in managing a disease state should be available to the physician and pharmacist when they create a collaborative agreement and treatment protocol. She cites diabetes management as an example.

**Rodney L. Stiltner, Pharm.D., Director, Pharmacy Services, VCU Health System, Medical College of Virginia Hospitals, Clinical Associate Professor, VCU School of Pharmacy, Department of Pharmacy Services representing the Virginia Society of Health-System Pharmacists and the Colleges of Pharmacy (Appalachian, Hampton, Shenandoah, and VCU) - August 17, 2012**

Dr. Stiltner provided the Committee with additional information concerning the curriculum and prerequisites for the training of pharmacists. A minimum of 95 semester hours as specified in the following listing of courses is required prior to admission for students entering in the Fall semester. [3]

| | |
|---|---|
| General Biology (8 hrs.[4]: 6 lecture and 2 laboratory)<br>College Chemistry (8 hrs.: 6 lecture and 2 laboratory)<br>Organic Chemistry (8 hrs: 6 lecture and 2 laboratory)<br>Physics (4 hrs.: 3 lecture, 1 laboratory)<br>Human Anatomy (3 hrs. with 1 laboratory hr. preferred)<br>Human Physiology (3 hrs.)<br>Microbiology (3 hrs. with 1 laboratory hr. preferred)<br>Biochemistry (3 hrs.) | English (6 hrs.)<br>Calculus (3 hrs.)<br>Statistics (3 hrs.)<br>Public Speaking (3 hrs.)<br>Biomedical Science Foundation<br>and Elective Courses (35 hrs.) |

[3] Neither College Board Advanced Placement Tests nor International Baccalaureate program courses in math or science are accepted as fulfilling requirements.

[4] Hours listed are semester hours.

Dr. Stiltner reports that 95% of entering classes for the past several years have previously earned a bachelor's degree.

As discussed at the public hearing, Dr. Stiltner holds that patient medication related outcomes are improvable and health system costs reducible by optimizing collaborative practice agreements that comport with the six recommendations noted in Dr. Musselman's and Dr. Havrda's comments, above. He cites the findings described in the Chisholm-Burns et al (2010) meta-analysis study and the 2011 report to the U.S. Surgeon General referenced earlier. He further notes the American Academy of Family Physicians (AAFP) position paper on pharmacists.[5]

Dr. Stiltner references the Vision for the Future of Pharmacy adopted by the Joint Commission of Pharmacy Practitioners [6] and notes that pharmacy educators have been preparing pharmacy students for years to fulfill responsibilities for the rational use of medications contingent upon their authority and autonomy to manage medication therapy and communicate and collaborate with patients, caregivers, other health professionals, and qualified support personnel.

He also references success across the country in integrating pharmacists care within community health teams and the development of comprehensive medical homes through the Patient Safety and Clinical Pharmacy Services Collaborative supported by the Health Resources and Services Administration, Centers for Medicare and Medicaid Services and State Quality improvement Organizations. [7] He notes that his group believes that Congress envisioned in the *2010 Patient Protection and Affordable Care Act* a collaborative care model for Medicare recipients that incorporates medication management services to "manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing costs and hospital readmissions" and that this management includes selection or initiation of therapy if authorized by the states.

Dr. Stiltner notes that the recommended changes will allow prescribers who wish to implement team-based care to enter into "more comprehensive collaborative practice agreements as a means to optimize the efficiency of their patient centered team care medical home practice." He further states that "these changes should make these agreements more effective and increase their use by pharmacists and physicians and improve access, health outcomes and reduce costs associated with the provision of care in Virginia."

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[5] American Association of Family Practitioners. (December 2001 Board and 2003). Position paper: Pharmacists. Available at http://www.aafp.org/online/en/home/policy/policies/p/pharmacistspositionpaper.html.

[6] Joint Commission of Pharmacy Practitioners (2004, November). *Vision statement.* Available from the American College of Clinical Pharmacy's website http://www.accp.com/docs/positions/misc/JCPPVisionStatement.pdf

[7] U.S. Department of Health and Human Services Heaalth Resources and Services Administration Aptient Safety and Clinical Pharmacy Services Collaborative website: http://www.hrsa.gov/publichealth/clinical/patientsafety/index.html.

## Jackson, Laura (DHP)

**From:** Carter, Elizabeth A. (DHP)
**Sent:** Tuesday, July 24, 2012 2:58 PM
**To:** Silvester, Janet
**Cc:** Jackson, Laura (DHP)
**Subject:** RE: Follow up from the Public Hearing Yesterday

Dear Janet:

Thank you for your comments yesterday. Your answers were most helpful.

Because the study's aim is to address potential barriers to health team delivery, I believe it was clear to the Regulatory Research Committee members and staff you're your statements about "prescriptive authority" referred to collaborative initiation. But thank you for clarifying.

Your e-mail will be conveyed to the Committee along with all the written comment received until August 15, 2012.

Please let me know if you have any questions.

Very best regards,

Elizabeth

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**From:** Silvester, Janet [mailto:Janet.Silvester@mjh.org]
**Sent:** Tuesday, July 24, 2012 1:37 PM
**To:** Carter, Elizabeth A. (DHP)
**Subject:** Follow up from the Public Hearing Yesterday

Dr. Carter,

I wanted to follow-up with you regarding my comments yesterday and the intent of the Virginia Pharmacy Congress. Thank you so much for the opportunity to speak and for your thoughtful questions. I do want to be sure, however, that what we are talking about is clear. We are looking at including "initiation" of therapy in the language but only in the context of mutually agreed upon collaborative practice agreements which rest on protocols and treatment plans that have also been agreed upon in advance. We are ***not*** seeking independent prescriptive authority which I believe is a very different animal. Our desire has always been based solidly on a team based care model which we believe is best for the patient and best for the healthcare system as a whole. Please feel free to contact me at any time should I be able to help clarify anything. Thanks again for the opportunity and for the work you are doing.

Sincerely,

*Janet*

*Janet A. Silvester, RPh, MBA, FASHP*
*Director of Pharmacy and Emergency Services*
*Martha Jefferson Hospital*
*500 Martha Jefferson Drive*
*Charlottesville, VA 22911*
*Office: 434-654-7055*



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*Fax: 434-654-7060*
*email: janet.sllvester@mjh.org*

*A member of Sentara Healthcare*





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## Jackson, Laura (DHP)

**From:** Tim Musselman [tim@virginiapharmacists.org]
**Sent:** Friday, August 17, 2012 2:02 PM
**To:** Jackson, Laura (DHP)
**Cc:** Carter, Elizabeth A. (DHP); david.creecy@att.net; Kurt Bell; James Pickral
**Subject:** Virginia Pharmacists Association public comments - pharmacist scope of practice barriers to effective team delivery
**Attachments:** VirginiaPharmacistsAssociation_Collaborative-Agreements_Comments-8-17-12.pdf

Laura,

Please see attached comments from the Virginia Pharmacists Association for the Board of Health Profession's pharmacist scope of practice barriers to effective team delivery study.

Feel free to contact me if you have any questions.

- Tim

**Timothy S. Musselman, Pharm.D.**
Executive Director
Virginia Pharmacists Association
2530 Professional Road
North Chesterfield, VA 23235
Phone: 804-285-4145, ext 309
Fax: 804-285-4227
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VIRGINIA PHARMACISTS ASSOCIATION

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August 17, 2012

Elizabeth A. Carter, Ph.D.
Executive Director
Virginia Board of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Dr. Carter,

The Virginia Pharmacists Association appreciates the opportunity to provide comments in support of enhancing the Commonwealth's current collaborative agreements. Collaborative agreements in Virginia are voluntary and defined arrangements between a pharmacist and a prescriber following a specific protocol related to treatment using drug therapy, laboratory tests or medical devices for the purpose of improving patient outcomes. While there currently are active collaborative agreements occurring in Virginia between physicians and pharmacists, we feel that the utilization of collaborative agreements could be greatly increased with the following changes:

1. Patients may choose to opt out of a collaborative agreement rather than choosing to opt in.
    - Allowing patients to opt out of an agreement will allow for greater patient utilization of collaborative agreements.
2. Addition of disease-state specific protocols.
    - Currently protocols in Virginia are patient-specific. Greater flexibility will be gained by expanded protocols to include disease-state specific protocols as well.
3. Allowance for collaborative agreements to include all patients under the care of a physician or a physician group practice.
    - Currently, collaborative agreements are on a per-patient and per-physician basis. With the expansion of group practices and the introduction of Accountable Care Organizations and Patient-Center Medical Home models, the allowance for a medical director of a group practice to authorize a practice-wide collaborative agreement would greatly increase access to services provided under these partnerships.
4. Nurse Practitioners and Physician Assistants specifically listed as authorizers of agreements.
    - Because they will be part of patient care teams in the Commonwealth, it is important to include NPs and PAs in the language authorizing cooperative care provided by pharmacists to patients under a collaborative agreement.
5. Allowance for Electronic protocols.
    - Currently under collaborative agreements, protocols must be written. Since the adoption of Virginia's collaborative language in 1999, electronic technology in the medical field has increased substantially.

VPhA appreciates the opportunity to submit comments on enhancements to the current collaborative agreements. We feel as an organization that the changes suggested above will greatly increase utilization of collaborative agreements between prescribers and pharmacists and improve patient care delivery throughout the Commonwealth. Please feel free to reach out to us if you have any questions concerning these recommendations.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director
Virginia Pharmacists Association

**Jackson, Laura (DHP)**

**From:** Rodney Stiltner [rstiltner@mcvh-vcu.edu]
**Sent:** Friday, August 17, 2012 3:19 PM
**To:** Carter, Elizabeth A. (DHP)
**Cc:** Jackson, Laura (DHP)
**Subject:** Written Response - RRC - Pharmacy
**Attachments:** Comments to Virginia Board of Health Professions RRCAUG12 August 17 2012 final.docx

Hi Dr. Carter:

After the 7/23/2012, BHP public hearing, some pharmacy organizations have provided a written response for the Regulatory Research Committee. Please accept this written response from the Virginia Society of Health-System Pharmacists and the Colleges of Pharmacy in Virginia (Appalachian, Hampton, Shenadoah, and VCU).

See attachment for comments.

In addition, we are on our 2nd draft of the pharmacy technician scope of practice and will present that document to the BPH for review.

Thanks for your assistance and let me know if you have any comments.
Have a great weekend!
rodney

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August 17, 2012

Virginia Board of Health Professions
Regulatory Research Committee
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Members of the Committee:

During the public hearing on July 23rd, the Committee had some questions regarding the curriculum and the prerequisites for the training of pharmacists. In addition to the PharmD curricula provided in the study work we submitted to the Committee, we have included the prerequisites required prior to admission to the VCU School of Pharmacy as an attachment to this letter. Please note that over 95% of all those in the entering classes for the last several years have previously earned a bachelors degree.

As was noted in the comments from the Virginia Pharmacy Congress at the public hearing on July 23rd, we believe that patient medication related health outcomes can be improved and health system costs reduced through the transformation of pharmacy practice which incorporates the recommendations we are proposing to the scope of pharmacist practice. When pharmacists are integrated into direct patient care through collaborative practice agreements with physicians or other members of the healthcare team, patient care outcomes can be improved.

- According to a recent systematic review and meta-analysis of 298 research studies by Chisholm-Burns et al, integrating pharmacists into direct patient care results in improved outcomes across health care settings and disease states. These positive impacts have been seen in both inpatient care settings with reduced readmissions, reduced length of hospital stay and reduced mortality, as well as, in the ambulatory setting as evidenced by improvement in the attainment of clinical goals for patients with diabetes, heart failure, hypertension, dyslipidemias, and multiple other chronic diseases.
- As was articulated in the 2011 Report to the U.S. Surgeon General, following an initial diagnosis, pharmacist delivery of an array of patient care services in a variety of practice settings through collaborative practice agreements has led to significant improvements in patient outcomes.

In order to optimize the use of collaborative practice agreements in Virginia, we support the following changes to current collaborative practice language:

- ***Patients may choose to opt out of a collaborative agreement rather than choosing to opt in.***
    a. Allowing patients to opt out of an agreement will allow for greater patient utilization of collaborative agreements.
- ***Addition of disease-state specific protocols.***

a. Currently protocols in Virginia are patient-specific. We feel that the definition of an acceptable protocol be expanded to include disease-state specific protocols that are applicable to multiple patients.

- ***Allowance for collaborative agreements to include all patients under the care of a physician or a physician group practice.***
    a. Currently, collaborative agreements are stipulated to only be for a patient and authorized by a physician. With the expansion of group practices and the introduction of Accountable Care Organizations and Patient-Center Medical Home models, the allowance for a medical director of a group practice to authorize a practice-wide collaborative agreement would greatly increase access to services provided under these collaborative practice agreements.
- ***Nurse Practitioners and Physician Assistants specifically listed as authorizers of agreements.***
    a. Because these providers are becoming a more important part of patient care teams in the Commonwealth, we feel that it is important to include NPs and PAs in the language as individual prescribers authorized to enter into a collaborative practice agreement.
- ***Allowance for Electronic protocols.***
    a. Currently collaborative practice agreements and the associated care protocols must be maintained in written format. Since the adoption of Virginia's collaborative language in 1999, electronic technology in the medical field has increased substantially and we therefore recommend that these protocols which are integral to the collaborative practice agreement be able to be implemented and maintained as electronic documents.

In addition to these changes, we encourage active consideration of the expansion of existing collaborative practice agreement regulations to allow prescribers to authorize pharmacists to *select, initiate, or implement drug therapy, following the provision of an initial diagnosis*, for those pharmacists working in team based practice settings. In a position paper on pharmacists the American Academy of Family Physicians (AAFP) stated that the concept of coordinated and team-based care is a foundational premise of integrated care models such as the patient-centered medical homes (PCMHs) and accountable care organizations (ACOs). The AAFP position paper stated that "The AAFP supports arrangements where the pharmacist is part of an integrated team-based approach to care."

There is also a growing body of evidence, which is summarized in the Chisholm–Burns et al and 2012 Public health services pharmacists report to the Surgeon General, that medication management programs can make positive contributions to patient health and reduce the costs associated with delivery of quality health care. In many of these studies, pharmacists led the medication management programs. These findings support the vision for pharmacy's future that was adopted by the Joint Commission of Pharmacy Practioners, which represents all of the national pharmacist organizations, in 2005 that "Pharmacists will have the authority and autonomy to manage medication therapy...and will communicate and collaborate with patients, caregivers, health care professionals, and qualified support personnel in fulfilling their responsibility for the rational use of medications." Those of us who are educators have been preparing student pharmacists to take on these responsibilities for years and we are confident that they can effectively collaborate with their health professional colleagues to advance the health of all Virginians.

Indeed, hundreds of pharmacists as part of the patient safety clinical pharmacy collaborative have been integrated into community health teams across the country with the support of the Health Services and Resources Administration, the Center for Medicare and Medicaid Services, and State Quality Improvement organizations. These initiatives have enhanced the development of comprehensive medical homes which have increased patient access to comprehensive, community based, coordinated care. Finally we believe it is noteworthy that Congress envisioned a collaborative care model along the lines we are recommending for Medicare recipients in the 2010 Patient Protection and Accountable Care Act, where the desired medication management services to manage chronic disease, reduce medical errors, and improve patient adherence to therapies while reducing costs and hospital readmissions includes selection or initiation of therapy if authorized by the states.

We are grateful for the opportunity to share our perspectives regarding the current pharmacist scope of practice. Changes in the collaborative practice agreement language will allow those prescribers who desire to implement team-based care to enter into more comprehensive collaborative practice agreements as a means to optimize the efficiency of their patient centered team care medical home practice. These changes should make these agreements more effective and increase their use by pharmacists and physicians and improve access, health outcomes and reduce costs associated with the provision of care for Virginians.

Thank you for the opportunity to share our vision for the future,

Sincerely,

The Virginia Society of Health System Pharmacists

Appalachian College of Pharmacy

Hampton University School of Pharmacy

Shenandoah University School of Pharmacy

Virginia Commonwealth University School of Pharmacy

Attachment

The following prerequisite courses must be completed prior to admission for students entering in the Fall semester at Virginia Commonwealth University School of Pharmacy. Courses earned through Advanced Placement Tests of the College Board or an International Baccalaureate program will not be accepted to fulfill prerequisite science and math courses.

| | |
|---|---|
| | General Biology (6 SH lecture and 2 SH laboratory) |
| 8 SH | College Chemistry (6 SH lecture and 2 SH laboratory) |
| 8 SH | Organic Chemistry (6 SH lecture and 2 SH laboratory) |
| 4 SH | Physics (3 SH lecture and 1 SH laboratory) |
| 3 SH | Human Anatomy (also, 1 SH lab is preferred) |
| 3 SH | Human Physiology |
| 3 SH | Microbiology (also, 1 SH lab is preferred) |
| 3 SH | Biochemistry |
| 6 SH | English [1] |
| 3 SH | Calculus |
| 3 SH | Statistics |
| 3 SH | Public Speaking |
| 35 SH | Biomedical Science Foundation and Elective Courses[2-3] |
| **90 SH** | **Minimum Total** |

## Jackson, Laura (DHP)

**From:** Havrda, Dawn [dhavrda@su.edu]
**Sent:** Friday, August 17, 2012 4:05 PM
**To:** Jackson, Laura (DHP)
**Cc:** Alan McKay
**Subject:** Shenandoah University School of Pharmacy comments for collaborative agreements
**Attachments:** SU recommendations for CPA language 8 17 2012.pdf

Dear Laura,
Please find recommendations attached on behalf of Shenandoah University Bernard J. Dunn School of Pharmacy for modifications to the collaborative agreements. Thank you for the opportunity to submit our recommendations.

Dawn Havrda

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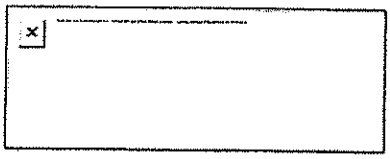



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SHENANDOAH™
UNIVERSITY
Bernard J. Dunn School of Pharmacy

August 17, 2012

Elizabeth A. Carter, Ph.D.
Executive Director
Virginia Board of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Dr. Carter:

Shenandoah University Bernard J. Dunn School of Pharmacy appreciates the opportunity to provide comments in support of enhancing the Commonwealth's current collaborative practice agreements. In Virginia, collaborative practice agreements are voluntary and define the relationship between a pharmacist and a prescriber to provide patient care services. These agreements may be related to treatment using drug therapy, laboratory tests or medical devices for the purpose of improving patient outcomes using a specific protocol. While active collaborative agreements in Virginia exist between physicians and pharmacists, we feel that needed changes to the regulations could increase the effective utilization of collaborative agreements. In addition, with the up-coming reforms to health care with the Accountable Care Act, there will be a greater demand for health care services and there is a projected shortage of physicians to meet the demand. Pharmacists, as the most accessible health care provider, are not only academically prepared, but ready and able to work collaboratively with physicians to assist with the patient care demand and the projected health care void. To allow pharmacists to serve in this capacity, we recommend the following changes be considered to the collaborative practice agreement regulations:

- Addition of "implementation" and/or "initiation" of drug therapy as an option for the collaborative agreement between the pharmacist and physician for post-diagnosis management of a medical condition.
    a. Pharmacists are uniquely positioned to work in conjunction with physicians in managing the drug therapy of a chronic disease state after the physician has diagnosed the patient. This allows the physician to focus on other aspects of the patient's care. All options in managing a disease state should be available to the pharmacist and physician when creating the collaborative agreement and treatment protocol.
    b. For instance, a physician can refer a patient with diabetes to a pharmacist, in which there is a collaborative agreement in place, to manage drug therapy to help the patient achieve the desired level of glycemic control. Given the numerous options for treatment of diabetes, a pharmacist can take the extra time to work with the patient and determine the optimal therapy based on patient desires, characteristics, other disease states, and laboratory results. As allowed by the physician, an option to initiate and/or implement drug therapy should be provided as a potential management strategy that the pharmacist could use per the approved disease state protocol.

- Allow patients to "opt out" of a collaborative agreement rather than choosing to "opt in."
    a. Allowing patients to opt out of an agreement will allow for greater patient utilization of collaborative agreements and is consistent with other health care appointments when physicians refer patients. Patients always have the right not to follow through with a referred appointment.

- Addition of disease-state specific protocols.
    a. Currently protocols in Virginia are patient-specific. The protocols should be expanded to include disease-state specific protocols as well.

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- Allow for collaborative agreements to include all patients under the care of a physician or a physician group practice.
    a. Currently, collaborative agreements are on a per-patient and per-physician basis. With the expansion of group practices and the introduction of Accountable Care Organizations and Patient-Center Medical Home models, the allowance for a medical director of a group practice to authorize a practice-wide collaborative agreement would greatly increase access to services provided under these partnerships.

- Addition of Nurse Practitioners and Physician Assistants specifically as authorizers of agreements.
    a. Because midlevel providers will be part of patient care teams in the Commonwealth, it is important to include NPs and PAs in the language authorizing cooperative care provided by pharmacists to patients under a collaborative agreement.

- Allow for electronic protocols.
    a. Currently under collaborative agreements, protocols must be written. Since the adoption of Virginia's collaborative language in 1999, electronic technology in the medical field has increased substantially.

On behalf of Shenandoah University Bernard J. Dunn School of Pharmacy, we appreciate the opportunity to submit comments on enhancements to the current collaborative agreements. We feel that the changes suggested above will greatly increase utilization of collaborative agreements between prescribers and pharmacists and improve patient care delivery throughout the Commonwealth now and in the future. Please feel free to contact us if you have any questions concerning these recommendations.

Sincerely,

Dawn Havrda

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# Virginia Board of Pharmacy

## Dispensing with an Authorized Generic

"Authorized generic" is defined in 21CFR314.3 as a listed drug that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug. Authorized generics may appear as a generic which could be deemed therapeutically equivalent by the Food and Drug Administration's (FDA) Orange Book, but they are actually manufactured and marketed by (or under licensing agreement with) the holder of the New Drug Application (NDA) for the brand-name product. Because the brand-name product is being marketed as a generic through an agreement, a second application to the FDA for generic approval is not required since it is the same drug that has already received approval under a NDA. Therefore, authorized generics are not classified as a therapeutically equivalent drug product and confusion exists as to whether a pharmacist may dispense an authorized generic when the prescription is written for a brand-name drug.

Because authorized generics are the same drug as the brand-name drug product, containing both the same active and inactive ingredients, it is reasonable that a pharmacist may dispense an authorized generic for a prescription written for a brand-name drug product when the prescriber does not otherwise prohibit substitution and the patient does not insist on the dispensing of the brand-name drug product. When an authorized generic is dispensed for the prescribed brand-name drug product, the pharmacist shall inform the patient or patient's agent either verbally or in writing that an authorized generic has been dispensed. The FDA provides a listing of authorized generics at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.

***Related statutes:***

**§54.1-3401**

*"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."*

**§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.**

*A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.*

*In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.*

*B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.*

*C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.*

*D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.*

# Virginia Board of Pharmacy

## COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained ~~for 2 years from the date performed.~~ in accordance with USP standards. Such records may be maintained ~~in offsite storage or~~ as an electronic image that provides an exact image of the document that is clearly legible provided such ~~offsite or~~ electronic ~~storage~~ image is retrievable and made available at the time of ~~for~~ inspection or audit ~~within 48 hours of a request~~ by the Board or an authorized agent.